General

Guideline Title

Guideline for sterilization.

Bibliographic Source(s)

Spry C, Conner R. Guideline for sterilization. In: 2015 guidelines for perioperative practice. Denver (CO): Association of periOperative Registered Nurses (AORN); 2012 Jun. p. 665-92. [60 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

I. Patient care items should be processed for reuse based on the intended use of the item.
II. Devices labeled as single-use should not be reprocessed unless the U.S. Food and Drug Administration (FDA) guidelines for reprocessing of single-use devices can be met.
III. Items to be sterilized should be cleaned, decontaminated, inspected, packaged, sterilized, and stored in a controlled environment and in accordance with the Association of periOperative Registered Nurses (AORN) "Guideline for cleaning and care of surgical instruments" (AORN, 2015) and the device manufacturer's validated and written instructions for use.
IV. Items to be sterilized should be inspected for cleanliness and proper function in accordance with AORN's "Guideline for cleaning and care of surgical instruments" (AORN, 2015).
V. Items to be sterilized should be packaged in a manner that promotes successful sterilization. Items should be packaged in accordance with AORN's "Guideline for selection and use of packaging systems for sterilization." (Spry & Conner, 2013).
VI. Saturated steam under pressure should be used to sterilize heat- and moisture-stable items unless otherwise indicated by the device manufacturer (Rutala & Weber, 2008).
VII. Immediate use steam sterilization (IUSS) should be kept to a minimum and should be used only in selected clinical situations and in a controlled manner (Association for the Advancement of Medical Instrumentation [AAMI] et al., 2012; Mangram et al., 1999).
VIII. Ethylene oxide sterilization is a low-temperature process that may be used for moisture- and heat-sensitive surgical items and when indicated by the device manufacturer.
IX. Low-temperature hydrogen peroxide gas plasma sterilization methods should be used to sterilize moisture- and heat-sensitive items and when indicated by the device manufacturer (AAMI, 2005).
X. Low-temperature hydrogen peroxide vapor sterilization methods should be used for moisture- and heat-sensitive items and when indicated by the device manufacturer.
XI. Sterilization systems using ozone should be used for moisture- and heat-sensitive items when indicated by the device manufacturer.

XII. Dry-heat sterilization should be used only for materials that are impenetrable to moist heat (Rutala & Weber, 2008). Dry heat may be used to sterilize anhydrous (i.e., waterless) items that can withstand high temperatures and when indicated by the device manufacturer.
XIII. Liquid chemical sterilant instrument processing systems that use peracetic acid as a low-temperature sterilant should be used for devices that are heat-sensitive, can be immersed, are approved for this process by the device manufacturer, and cannot be sterilized using terminal sterilization methods (STERIS Corp, 2010; FDA, 2011).
XIV. A formalized program between the health care organization and health care industry representatives should be established for the receipt and use of loaned instrumentation (Winthrop, Sion, & Gaines, 2007).
XV. Sterilized materials should be labeled and stored in a manner to ensure sterility, and each item should be marked with the sterilization date (AAMI, 2011).
XVI. Transportation of sterile items should be controlled.
XVII. Personnel should receive initial and ongoing education and competency validation for sterilization practices.
XVIII. Documentation should reflect activities related to sterilization (AAMI, 2011).
XIX. Policies and procedures for sterilization and sterilization-related processes and practices should be developed, reviewed periodically, revised as necessary, and readily available in the practice setting.
XX. A quality assurance and performance improvement process should be in place to measure patient, process, and system outcome indicators.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Any condition requiring the use of surgical and other invasive procedure–related critical medical devices

Guideline Category

Prevention

Clinical Specialty

Nursing

Preventive Medicine

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Guideline Objective(s)

- To provide guidance for sterilizing critical medical devices (per the Spaulding classification system) to be used in the perioperative setting
- To provide guidelines adaptable to various practice settings, including traditional operating rooms (ORs), ambulatory surgery centers, physicians' offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, and all other areas where surgery and

other invasive procedures may be performed

Note: Processing of noncritical and semicritical devices is outside the scope of this document.

Target Population

Patients undergoing surgical and other invasive procedures that require the use of critical medical devices (per the Spaulding classification system)

Interventions and Practices Considered

1. Determination of suitability of the device for reuse
2. Requirements for reprocessing single-use items (not generally recommended)
3. Environmental controls (manufacturer's instructions, workflow, personal protective equipment, monitoring the environment, timing of decontamination)
4. Device inspection for cleanliness and function
5. Preparation for sterilization (per manufacturer's specifications, packaging, tray weight, equipment setup)
6. Choice of sterilization method applicable to device:
    - Steam
    - Immediate use steam sterilization (IUSS) (generally not recommended for implantable devices; not recommended to replace adequate supplies)
    - Ethylene oxide
    - Hydrogen peroxide gas plasma or vapor
    - Ozone
    - Dry heat
    - Liquid chemical sterilant (peracetic acid), with proper rinsing
7. Cycle parameters (sterilization time, drying time)
8. Monitoring the sterilization process (physical monitors [e.g., printouts, digital readings, graphs, gauges], chemical indicators, and biological indicators)
9. Delivery of sterilized devices
10. Documentation of sterilization process, with additional documentation for IUSS
11. Health and safety procedures for personnel
12. Receipt and use of loaned instruments
13. Labeling and storage of sterilized items
14. Transportation of sterile items
15. Education and competency validation
16. Documentation of sterilization-related activities
17. Development and review of policies and procedures for sterilization and sterilization-related processes
18. Quality assurance and performance improvement processes

Major Outcomes Considered

- Rate of surgical site infection associated with sterilization failure of critical medical devices
- Number of personnel affected by improper sterilization procedures (e.g., ethylene oxide exposure, injury from overly heavy trays)
- Rate of immediate use steam sterilization
- Rate of sterilization operating and processing errors
- Availability of ongoing education for personnel

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A medical librarian conducted a systematic literature search of the databases MEDLINE®, CINAHL®, Scopus®, and Cochrane Database of Systematic Reviews for meta-analyses, randomized and non-randomized trials and studies, systematic and non-systematic reviews, and opinion documents and letters. Search terms included *sterilization, ethylene oxide, steam, peracetic acid, dry heat, hydrogen peroxide gas, ozone, hospital equipment and supplies, prostheses and implants, surgical equipment, infusion pumps, disposable equipment, diagnostic equipment, flash sterilization, immediate use, surgical equipment and supplies, equipment contamination, microbial contamination, indicators and reagents, fungi, bacterial contamination, ethylene oxide toxicity*, and *biofilms*, as applicable.

The search was limited to articles published in English between 2005 and 2011. Older articles were included where there were no articles within this time period. Additional articles not identified in the original literature search were obtained by reviewing the reference lists of the original articles.

The librarian also established continuing alerts on the sterilization topics. The lead author and medical librarian identified relevant documents from government agencies, standards-setting bodies, and equipment manufacturers, with the lead author requesting other guidelines, professional literature, and book chapters as necessary.

Number of Source Documents

Seventy-five articles met the inclusion criteria and were included in the review.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Not Given)

Rating Scheme for the Strength of the Evidence

Not stated

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Articles identified by the search were provided to the project team for evaluation. The team consisted of the lead author, two members of the Recommended Practices Advisory Board, two members of the Research Committee, and an ad hoc member of the Evidence Rating Task Force. The lead author divided the search results into topics and assigned members of the team to review and critically appraise each article using the Johns Hopkins Evidence-Based Practice Model and the Research or Non-Research Evidence Appraisal Tools as appropriate. The literature was independently evaluated and appraised according to the strength and quality of the evidence. Each article was then assigned an appraisal score as agreed upon by consensus of the team. The appraisal score is noted in brackets after each reference citation, as applicable.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The collective evidence supporting each intervention within a specific recommendation was summarized and used to rate the strength of the evidence using the Oncology Nursing Society Putting Evidence into Practice (ONS PEP®) schema. Factors considered in review of the collective evidence were the quality of research, quantity of similar studies on a given topic, and consistency of results supporting a recommendation. The evidence rating is noted in brackets after each intervention.

Rating Scheme for the Strength of the Recommendations

1: Strong Evidence: Interventions or activities for which effectiveness has been demonstrated by strong evidence from rigorously-designed studies, meta-analyses, or systematic reviews, rigorously-developed clinical practice guidelines, or regulatory requirements.

- Evidence from a meta-analysis or systematic review of research studies that incorporated evidence appraisal and synthesis of the evidence in the analysis.
- Supportive evidence from a single well-conducted randomized controlled trial.
- Guidelines that are developed by a panel of experts, that derive from an explicit literature search methodology, and include evidence appraisal and synthesis of the evidence.

1: Regulatory Requirement: Federal law or regulation.

2: Moderate Evidence: Interventions or activities for which the evidence is less well established than for those listed under "Strong Evidence."

- Supportive evidence from a well-conducted research study.
- Guidelines developed by a panel of experts which are primarily based on the evidence but not supported by evidence appraisal and synthesis of the evidence.
- Non-research evidence with consistent results and fairly definitive conclusions.

3: Limited Evidence: Interventions or activities for which there is currently insufficient evidence or evidence of inadequate quality.

- Supportive evidence from a poorly conducted research study.
- Evidence from non-experimental studies with high potential for bias.
- Guidelines developed largely by consensus or expert opinion.
- Non-research evidence with insufficient evidence or inconsistent results.
- Conflicting evidence, but where the preponderance of the evidence supports the recommendation.

4: Benefits Balanced With Harms: Selected interventions or activities for which the Association of periOperative Registered Nurses (AORN) Recommended Practices Advisory Board (RPAB) is of the opinion that the desirable effects of following this recommendation outweigh the harms.

5: No Evidence: Interventions or activities for which no supportive evidence was found during the literature search completed for the recommendation.

- Consensus opinion

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Not stated

Evidence Supporting the Recommendations

References Supporting the Recommendations

Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care, Inc, AORN, et al. Immediate-use steam sterilization statement. [internet]. [accessed 2012 Apr 25].

Association for the Advancement of Medical Instrumentation (AAMI). ANSI/AAMI ST58: Chemical sterilization and high-level disinfection in health care facilities. Arlington (VA): Association for the Advancement of Medical Instrumentation (AAMI); 2005.

Association for the Advancement of Medical Instrumentation (AAMI). ANSI/AAMI ST79:2010/A2:2011: Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Arlington (VA): Association for the Advancement of Medical Instrumentation (AAMI); 2011.

Guideline for cleaning and care of surgical instruments. In: 2015 guidelines for perioperative practice. Denver (CO): Association of periOperative Registered Nurses (AORN); 2015. p. 615-50.

Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR, Hospital Infection Control Practices Advisory Committee. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol. 1999 Apr;20(4):250-78; quiz 279-80. [497 references] PubMed

Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2008. 158 p.

Spry C, Conner R. Guideline for selection and use of packaging systems for sterilization. In: 2015 guidelines for perioperative practice. Denver (CO): Association of periOperative Registered Nurses (AORN); 2013 Sep. p. 651-64. [56 references]

STERIS Corp. Revised 510(k) Summary for SYSTEM 1E Liquid Chemical Sterilant Processing System. Mentor (OH): STERIS Corp.; 2010.

U.S. Food and Drug Administration. STERIS System 1E (SS1E) liquid chemical sterilant - K090036. [internet]. 2011 Jun 30 [accessed 2012 Apr 25].

Winthrop TG, Sion BA, Gaines C. Loaner instrumentation: processing the unknown. AORN J. 2007 Mar;85(3):566-73. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Prevention of infections at the sites of perioperative use of critical medical devices

Potential Harms

- Ethylene oxide is a known human carcinogen and a chemical that has the potential to cause adverse reproductive effects in humans. The Occupational Health and Safety Administration (OSHA) has established exposure limits for ethylene oxide in the workplace.
- If not removed, ethylene oxide residue absorbed into sterilized items represents a hazard to patients and personnel. Items that are not sufficiently aerated may cause patient or personnel injury (e.g., chemical burns).
- Rinsing an inadequately aerated item does not remove ethylene oxide and can create hazardous by-products.
- Serious injuries (e.g., burns) may result if peracetic acid is not handled, neutralized, and rinsed properly. Peracetic acid is corrosive to the skin at concentrations of 3.4% or higher and corrosive to the eyes at concentrations of 0.35% or higher.

Qualifying Statements

Qualifying Statements

- These recommended practices represent the Association of periOperative Registered Nurses's (AORN's) official position on questions regarding optimal perioperative nursing practice.
- No attempt has been made to gain consensus among users, manufacturers, and consumers of any material or product.
- Compliance with the AORN recommended practices is voluntary.
- AORN's recommended practices are intended as achievable and represent what is believed to be an optimal level of patient care within surgical and invasive procedure settings.
- Although they are considered to represent the optimal level of practice, variations in practice settings and clinical situations may limit the degree to which each recommendation can be implemented.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Jun

Guideline Developer(s)

Association of periOperative Registered Nurses - Professional Association

Source(s) of Funding

Association of periOperative Registered Nurses

Guideline Committee

Association of periOperative Registered Nurses (AORN) Recommended Practices Advisory Board

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Financial Disclosures/Conflicts of Interest

No financial relationships relevant to the content of this guideline have been disclosed by the authors, planners, peer reviewers, or staff.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Not available at this time.

Print copies: Available from the Association of periOperative Registered Nurses (AORN) Web site .

Availability of Companion Documents

The following is available:

- Sterilization recommended practices: based on evidence. Webinar. Available from the Association of periOperative Nurses (AORN) Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on September 5, 2012. The information was verified by the guideline developer on October 2, 2012.

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